REPORT TITLE

Endosulfan Task Force Response to EPA's Memorandum titled "α- and β-Endosulfan and Endosulfan-sulfate: Drinking Water EECs for Use in the Human Health Risk Assessment" (Agency/EFED Memo dated April 18, 2000)

DATA REQUIREMENT

Not Applicable

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

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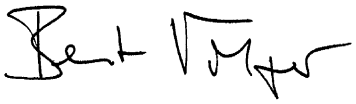

Signature:

Date: July 12, 2000

1. STATEMENT OF GOOD LABORATORY PRACTICE

No Good Laboratory Practice Statement is required for the information presented in this report according to 40CFR Part 160.

Submitter: _____

Bert Volger, Ph. D.
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Date: July 12, 2000

Endosulfan Task Force Response to EPA's Memorandum titled "α- and β-Endosulfan and Endosulfan-sulfate: Drinking Water EECs for Use in the Human Health Risk Assessment" (Agency/EFED Memo dated April 18, 2000)

1. Introduction

On behalf of the Endosulfan Task Force (ETF), consisting of Aventis CropScience USA LP, FMC Corporation, and Makhteshim-Agan of North America, AgrEvo[♣] USA submitted in October, 1999 four reports related to *'Tier-II Surface Water Exposure Assessment for Endosulfan'* (MRID Nos.: 44953101, 44953102, 44953103, 44953104), and one report concerning the *'Calculation of Dietary Exposure to Endosulfan via Drinking Water and Comparison to Drinking Water Level of Concern'* (MRID No: 44953105). On November 17, 1999, AgrEvo received from the Reregistration Division an Agency memo titled *"Endosulfan: Refined Surface Water EEC's for Use in Human Health Risk Assessment"* prepared by Dr. Dirk Young of EFED, dated October 28, 1999. In response Aventis CropScience conducted a detailed review of the subject and submitted a response to EPA on January 31, 2000.

The ETF received the preliminary HED dietary risk assessment for endosulfan for the RED document in April 2000 (DP Barcode: D250471; Memo by Stephen C. DeVito, Ph.D., and dated February 17, 2000 - Exposure Assessment, Section 4.3 "Risks from Dietary Food and Drinking Water Sources Exposure to Endosulfan"). The ETF submitted a detailed response to HED's draft chapter on May 11, 2000, titled *"The 30-Day Response by the Endosulfan Task Force to the Health Effects Division Risk Assessment for the Endosulfan Reregistration Eligibility Decision Document Dated February 2, 2000"* (MRID No: 451224-00).

On May 22, 2000 Aventis CropScience received from the Reregistration Division an Agency memo titled "*α- and β-Endosulfan and Endosulfan-sulfate: Drinking Water EECs for use in the human health risk assessment*" prepared by Dr. Dirk Young of EFED, dated April 18, 2000. This memo summarized the Tier II exposure assessment for endosulfan concerning its use in the human health risk assessment. The exposure assessment included new methods and protocols for drinking water exposure assessments but did not consider any of the concerns we expressed in our January 31, 2000 response. Therefore, the ETF is submitting the following comments with specific reference to our submitted PRZM/EXAMS modeling reports and our comments dated January 31, 2000. We respectfully request that EFED will incorporate this current information in the ongoing endosulfan RED process and will also update the EEC calculations in surface water and groundwater accordingly.

[♣] Effective December 15, 1999, AgrEvo USA Company and Rhone-Poulence Agro have merged to form Aventis CropScience USA LP

2. Points of Concern

The following are the concerns we have in the EPA's DWEC calculations. Each of the points are discussed in detail in the following sections:

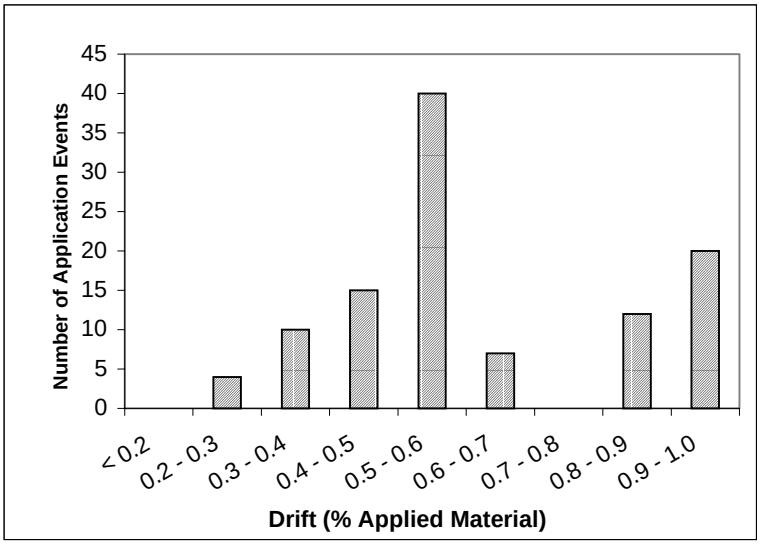
- Impact of 300 ft. no-spray buffer
- Selection of product-specific environmental fate parameters
- Selection of appropriate runoff curve numbers

2.1 Impact of No-Spray Buffer

The use-restriction of a 300-ft buffer as required by the ETF end-use product labels should be considered in the surface water exposure assessment. This buffer reduces the potential endosulfan loading through drift and runoff significantly.

A drift value of 16 % was used in the EPA surface water exposure assessment. This value does not reflect the label restriction of a 300 ft. no-spray buffer. The drift estimates used in AgrEvo's exposure assessment considered the presence of a 300-ft no-spray buffer between a treated field and a water body. This procedure used a probabilistic controlled-selection approach utilizing more sophisticated capabilities available in the Tier II option of AgDrift, and using realistic meteorological parameters relevant to the exposure scenario. The procedure is explained in detail in the Aventis CropScience Report B002255 (MRID No: 44953103)[2] ,. It also follows some of the draft recommendations of ECOFRAM. The probabilistic distribution of estimated drift occurring during the simulated aerial applications to cotton in MLRA 134 (Lower Mississippi Uplands) with the PRZM/EXAMS model, is illustrated below:

Drift (%)	No. of Events
< 0.2	0
0.2 - 0.3	4
0.3 - 0.4	10
0.4 - 0.5	15
0.5 - 0.6	40
0.6 - 0.7	7
0.7 - 0.8	0
0.8 - 0.9	12
0.9 - 1.0	20
> 1.0	0



The above table and figure demonstrate that the maximum estimated drift using the meteorological parameters from Shreveport, LA was 1 % using a 300-ft buffer. Based on these calculations the estimated EECs will be significantly lower than those calculated by EPA assuming 16% drift.

2.2 Environmental Parameters

The selection of input parameters for the degradation of endosulfan isomers (α- and β-endosulfan) and endosulfan-sulfate in soil and water has a significant impact on the exposure assessments. Since the ecotoxicological endpoints and sorption properties of α- and β-endosulfan and endosulfan-sulfate are similar, we consider it more appropriate to evaluate the environmental fate and exposure of these three compounds as 'total endosulfan' residues.

2.2.1 Soil degradation

The soil degradation rates used in the exposure assessment conducted earlier by AgrEvo were derived from the Georgia and California field dissipation studies (MRID Nos.: 41309702 and 41468601).[3, 4] Stumpf et al. (Report: A53618; MRID: 43812801)[5] conducted an aerobic soil metabolism study and noted that degradation rates derived from the referenced field dissipation studies need to be used in the exposure assessments because the microbial activity in the small-sized laboratory samples became slow or dormant after about 180 days unlike in field conditions, where it will be abundant. In addition, it is more appropriate to use the degradation rates from these field dissipation studies for the exposure assessments because they implicitly include the soil metabolism, hydrolysis, photolysis, biolysis and volatilization. The soil degradation half-life used in AgrEvo's exposure assessment was 150 days for total endosulfan (which included endosulfan-sulfate), compared to 57 days and 208 days for α- and β-endosulfan, respectively, used by EFED.

2.2.2 Aquatic degradation

The EPA exposure assessment assumed that the aerobic aquatic half-life be twice that of the aerobic soil half-life (114 days and 416 days, respectively for α- and β-endosulfan). The results from a recently submitted aerobic sediment-water study show that the values used by EPA are not appropriate. The half-life of α- and β-endosulfan in the total sediment-water system (Gildemeister, Report: A31182; MRID: 44917801)[6] was 4 to 8 days. The half-life of total endosulfan (α- and β-endosulfan plus endosulfan-sulfate) in the sediment-water from the same study was determined to be 18.5 to 21 days (Report: B002224; MRID: 44953102)[7], and a value of 19 days was used in AgrEvo's exposure assessment.

2.2.3 PRBEN (PRoportion of sorbed chemical delivery to BENthic zone)

PRBEN is a parameter used in the EXAMS model. PRBEN determines the proportion of sorbed material loaded into the water body going to the benthic sediment. The estimated EECs were found sensitive to this parameter (Report B002224, MRID No: 44953102)[7]. The default value for PRBEN in EXAMS is 0.5, indication that 50 % of the sorbed material in runoff goes into the benthic sediment and the rest to the dissolved phase. This value is not appropriate for a compound with a high partition coefficient like endosulfan. For Tralomethrin, a synthetic pyrethroid, having similar sorption characteristics as endosulfan, a value of 0.92 was determined for PRBEN using the data obtained from a microcosm study (Report: A47913; MRID: 42773904)[8]. In the endosulfan exposure assessment conducted by AgrEvo, a PRBEN value of 0.9 was used. The value of PRBEN used in the EPA exposure assessment was not disclosed or provided to us.

2.3 Runoff Curve Numbers

The curve numbers used by EPA are high and unrealistic, particularly for the first year in the 3-year rotation simulated. The curve numbers recommended by EPA in the FEMVTF – Level 1 guidelines are similar to the ones used in the AgrEvo exposure assessment (Report: B002255, MRID No:44953103)[2]. The following table summarizes the curve numbers used by EPA and AgrEvo in their assessments and also lists the EPA-recommended values for FEMVTF – Level 1 validations.

Year in Rotation	EPA			AgrEvo			FEMVTF – Level 1		
	Fallow	Crop	Residue	Fallow	Crop	Residue	Fallow	Crop	Residue
1st Year (Conventional Till)	99	93	92	91	88	88	91	87	87
2nd Year (No-Till)	94	84	83	88	84	84	91	84	84
3rd Year (No-Till)	99	83	83	88	82	83	91	84	84

It can be noted that the discrepancies between the EPA values and AgrEvo values are mainly in the first year of the 3-year rotation. A comparative analysis was conducted using both the curve number regimes. The simulation using EPA curve numbers resulted in 13 % to 27 % (mean 19 %) higher endosulfan loads than the simulation using AgrEvo curve numbers during the first of the 3-year rotation. We believe that the curve numbers used by AgrEvo are realistic and EPA's exposure simulation should be rerun using the more appropriate curve numbers.

3. Conclusion

We agree that the worst-case exposure scenario for endosulfan exposure assessment is the Mississippi cotton scenario (in MLRA 134) with a percent crop area of 20, which seems more appropriate. However, the generic assumptions in the standard index reservoir for Mississippi cotton are not appropriate to use for the endosulfan exposure assessment because of the specific label restrictions and specific environmental characteristics of the compound.

The EECs from AgrEvo's exposure assessments (from Report B002255, MRID No:4495103)[2] for acute and chronic exposure to total endosulfan residues (α-, β-endosulfan and endosulfan-sulfate) are summarized below:

Scenario	90th Percentile Estimated Dissolved Exposure Concentration (µg/L) of Total Endosulfan from a 36-year Simulation of Endosulfan Application					
	Instant-aneous	96-hour	21-day	60-day	90-day	Annual Average
Cotton in MLRA 134 (Aerial Application; 3 x 1.12 kg a.i./ha)	0.89	0.59	0.27	0.17	0.13	0.05

The HED dietary risk assessment document (DP Barcode: D250471; Memo by Stephen C. DeVito, Ph.D., dated February 17, 2000 - Exposure Assessment, Section 4.3 ; Page 35) notes that the historically observed maximum peak concentration of endosulfan in the monitored water bodies from the STORET and NLM's HSDB databases covering the US and Canada since the early 1970s is 0.9 µg/L. This value is comparable to the EECs predicted as the worst case in the exposure assessment conducted by AgrEvo. Although the Drinking Water Exposure Concentrations (DWECs) estimated by EFED do not exceed the calculated Drinking Water Level of Comparison (DWLOC), it is still important for the record, that the Agency should use DWEC values that account for the 300 foot buffer as required by the ETF end-use product labels for endosulfan. We appreciate your consideration regarding this matter to make the assessments better reflect the use of the product in the field.

4. References

1. "Endosulfan: Calculation of Dietary Exposure via Drinking Water and Comparison to Drinking Water Level of Concern (DWLOC)", by Richard Allen. October 8,1999. Environmental Chemistry Department, AgrEvo USA Company. *(Aventis CropScience Document No.: B002594)* AgrEvo GmbH. MRID No.: 44953105.

2. "Endosulfan (AE F002671): Tier II Surface Water Exposure Assessment and Comparison to Acute Toxicity End-Points", by T.S. Ramanarayanan, R. Allen, and R.W. Fischer. October 15, 1999. Environmental Chemistry Department, AgrEvo USA Company *(Aventis CropScience Document No.: B002255).* MRID No.: 44953103.

3. "Endosulfan (Thiodan 3EC): Field Dissipation of Terrestrial Uses on Tomatoes in Georgia, USA", by L. A. Hacker. 1989. Landis Associates Inc. and Hoechst AG. (*Aventis CropScience Document No. A42193*). MRID No.: 41309702

4. "Final Report Endosulfan (LX165-03) Terrestrial/Runoff. Study on Cotton in California with Furrow Irrigation". By T.C. Mester. 1990. Landis Associates Inc. and Hoechst AG. (*Aventis CropScience Document No. A42997*). MRID No.: 41468601

5. "Metabolism of ^{14}C-Labeled Endosulfan in Five Soils Under Aerobic Conditions", by K. Stumpf, P. Dambach, and O. Lenz. April 6, 1995. Hoechst AgrEvo Schering GMBH (*Aventis CropScience Document No.: A 53618*). MRID No.: 43812801.

6. "Hoe 002671–^{14}C (Endosulfan): Aerobic Aquatic Metabolism Study with the Insecticide Endosulfan", by H. Gildemister, Hoechst Analytical Laboratory, Frankfurt, Germany. April 16, 1985. (*Aventis CropScience Document No*.: A31182; EPA GLN No.: 162-4). MRID No.: 44917801.

7. "Endosulfan (AE F002671): Tier II Exposure Assessment; Sensitivity Analysis for PRZM (Ver. 3.12), EXAMS (Ver. 2.97.5) and AgDrift (Ver. 1.02)", by T.S. Ramanarayanan and R. Allen. October 5, 1999. AgrEvo USA Company *(Aventis CropScience Document No.: B002224).* MRID No.: 44953102.

8. "Tralomethrin and Deltamethrin – Comparative Environmental Fate During an Aquatic Microcosm Test", by P. H. Fackler. September 27, 1991. Springborn Laboratories Inc. (*Aventis CropScience Document No*.: A47913). MRID No.: 42773904.